# **EXHIBIT A**

#### SETTLEMENT AGREEMENT AND RELEASE

# I. PARTIES

This Settlement Agreement ("Agreement") is entered into by the United States of America, acting through the United States Department of Justice and the United States Attorney's Office for the District of Massachusetts, and the Office of Inspector General ("OIG-HHS") of the United States Department of Health and Human Services ("HHS"); TRICARE Management Activity ("TMA")(formerly known as the Office of the Civilian Health and Medical Program of the Uniformed Services), a field activity of the Office of the Secretary of Defense, the United States Department of Defense; the Office of Personnel Management ("OPM"), which administers the Federal Employees Health Benefits Program ("FEHBP"); Schering-Plough Corporation ("Schering"), a New Jersey Corporation with a principal place of business in Kenilworth, New Jersey, and its subsidiaries and divisions, including Schering Sales Corporation, through their authorized representatives. Collectively, all of the above shall be referred to as "the Parties."

## II. PREAMBLE

A. WHEREAS, at all relevant times, Schering distributed, marketed and sold pharmaceutical products in the United States, including the following prescription drug products: (1) loratedine rapidly dissolving tablets, a non-sedating antihistamine, marketed under the brand name Claritin Redi-Tabs; (2) potassium chloride 20 meq, an electrolytic and water balance agent, marketed under the brand name K-Dur 20; (3) temozolomide, a chemotherapeutic agent, marketed under the brand name Temodar; (4) interferon alfa-2b, a biologic, marketed under the brand name PEG-Intron; (6) interferon alfa-2b marketed together with ribavirin, a nucleoside analogue, under the brand name

Rebetron; and (7) pegylated interferon alfa-2b marketed together with ribavirin as PEG-Intron Combination Therapy (collectively, "the drugs"). Schering sold the drugs to various customers including, among others, health maintenance organizations ("HMOs"), hospitals, long term care providers, chain pharmacies, specialty pharmacies, and physicians. One of the HMOs to which Schering sold drugs was Kaiser Permanente Medical Care Program ("Kaiser").

B. WHEREAS, Schering Sales Corporation, a wholly owned subsidiary of Schering-Plough Corporation, has agreed to enter into a plea agreement with the United States Attorney for the District of Massachusetts (the "Plea Agreement"), under which, if the Plea Agreement is approved by the Court, Schering Sales Corporation will enter a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) to an Information to be filed in <u>United States of America v. Schering Sales Corporation</u> (District of Massachusetts)(the "Criminal Action") that will allege that Schering Sales Corporation violated Title 18, United States Code, Section 371, by conspiring to make false statements in violation of Title 18, United States Code, Section 1001, to the Health Care Financing Administration ("HCFA") in connection with Schering's best price for Claritin Redi-Tabs for second quarter 1998 through fourth quarter 1999, and to the United States Food and Drug Administration ("FDA") in response to an inquiry by the FDA in July 2001 regarding Schering's off-label marketing activities.

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D. WHEREAS, at all material times, Schering participated in the Medicaid Rebate Program, 42 U.S.C. § 1396r-8, which is part of the federal Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v. As a participant in the Medicaid Rebate Program, Schering entered into a rebate agreement with HCFA, currently known as the Centers for Medicare and Medicaid Services ("CMS"), and Schering's drug products were covered by state Medicaid plans that provided medical assistance for outpatient prescription drugs. 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(12), and 1396r-8(a)(1). Under the Medicaid Rebate Program and rebate agreement with HCFA, Schering generally agreed: (i) to report quarterly to HCFA its average manufacturer price and, for single source and innovator multiple source drugs, best price for its drug products, as defined by 42 U.S.C. §§ 1396r-8(k)(1) and 1396r-8(c)(1)(C); and (ii) to pay quarterly rebates to the states based on the product of (a) the units of each dosage form and strength paid for under the State Medicaid plan during the rebate period as reported by the state, and (b) the greater of the difference between the average manufacturer price and best price, or a minimum rebate percentage of the average manufacturer price, as further defined in 42 U.S.C. § 1396r-8(c)(1).

E. WHEREAS, at all material times, Schering participated in the Drug Pricing Program, 42 U.S.C. § 256b, which is part of the Public Health Service ("PHS") Act, 42 U.S.C. §§ 201-300gg-92. As a participant in the Drug Pricing Program, Schering entered into an agreement with HHS in connection with the pricing of its drug products sold to entities such as AIDS drug purchasing assistance programs, community health centers, hemophilia treatment centers, and disproportionate

share hospitals, as defined in 42 U.S.C. § 256b(a)(4) (the "PHS entities"). Under the Drug Pricing Program and its agreement with HHS, Schering generally agreed that the amount that Schering required the PHS entities to pay for drug products would not exceed the average manufacturer price, as reported by Schering to HCFA in the previous calendar quarter, minus a specified rebate percentage that was derived in part from the Medicaid rebate paid by Schering in the preceding calendar quarter for each drug, as further described in 42 U.S.C. § 256b(a).

- F. WHEREAS, Schering has entered into or will be entering into separate settlement agreements (hereinafter referred to as the "Medicaid State Settlement Agreements") with the states which will be receiving settlement funds from Schering pursuant to Paragraph 1(B) below for the Covered Conduct described in Paragraph H below (hereinafter referred to as the "Medicaid Participating States").
- G. WHEREAS, the United States alleges that Schering caused to be submitted claims for payment for the drugs to the Medicaid Programs, established pursuant to or in connection with Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (the "Medicaid Program"); and the United States further alleges that Schering caused to be submitted claims for payment for the drugs to the Medicare Program, established pursuant to Title XVIII of the Social Security Act, § 1395-1395ggg, which is administered by HHS; the TRICARE Program (formerly known as the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS")), 10 U.S.C. §§ 1071-1106, which is administered by the Department of Defense through the TMA; the FEHBP, 5 U.S.C. §§ 8901-8914; and that Schering caused purchases of the drugs by the Department of Veterans' Affairs ("DVA").

- H. WHEREAS, the United States contends that it has certain civil claims against Schering under the False Claims Act, 31 U.S.C. §§ 3729-33, the Medicaid Rebate Program, 42 U.S.C. § 1396r-8, the Drug Pricing Program, 42 U.S.C. § 256b, other federal statutes, and/or common law doctrines as specified in Paragraph 2 below for engaging in the following conduct:
- (i) The United States contends that, from Second Quarter 1998 through Fourth Quarter 1999, Schering knowingly and willfully misreported its best price to HCFA and underpaid its Medicaid rebates for Claritin Redi-Tabs by omitting from its determination of best price the free Claritin Redi-Tabs contingent on future purchases that were provided to Kaiser to effectuate an agreed-upon lower price;
- (ii) The United States contends that, from First Quarter 2000 through Fourth Quarter 2001, Schering knowingly misreported its best price to HCFA and underpaid its Medicaid rebates for Claritin Redi-Tabs by omitting from its determination of best price deeply discounted Claritin Redi-Tabs that were provided to Kaiser to effectuate an agreed-upon lower price;
- (iii) The United States contends that, from Fourth Quarter 1995 through Fourth Quarter 2000, Schering knowingly misreported its best price to HCFA and underpaid its Medicaid rebates for K-Dur 20 by omitting from its determination of best price the price of K-Dur 20 that was private labeled for Kaiser;
- (iv) The United States contends that, from Fourth Quarter 1998 through Second Quarter 2002, Schering overcharged the PHS entities for Claritin Redi-Tabs; and from Second Quarter 1996 through Second Quarter 2001, Schering overcharged the PHS entities for K-Dur, as a result of Schering's misreporting of its best prices as described in Preamble Paragraphs H (i), (ii) and (iii), above;

- (v) The United States contends that, as part of Schering's sales and marketing practices for PEG-Intron, Rebetron, and PEG-Intron Combination Therapy for patients with Hepatitis C from January 1999 through December 2002, Schering knowingly and willfully offered and paid illegal remuneration to induce physicians to start patients on drug therapy for Hepatitis C in violation of 42 U.S.C. §1320a-7b(b)(2) through three improper sales and marketing programs: the ReCAP Program, which paid physicians up to \$500 for each patient begun on drug therapy for Hepatitis C; the Physician Assistants ("PA") Fellowship Program, which placed Schering-funded physician assistants in busy physician practices; and Low Quintile Advisory Board programs, which paid physicians for attendance at Schering-sponsored events. Furthermore, the Government contends that during this time period, Schering knowingly caused the submission of false or fraudulent claims to the Medicaid and TRICARE Programs for PEG-Intron, Rebetron, and PEG-Intron Combination Therapy, and caused the DVA to purchase PEG-Intron, Rebetron, and PEG-Intron Combination Therapy by providing physicians with illegal remuneration through these three programs to induce them to prescribe these drugs to patients;
- (vi) The United States contends that, as part of Schering's sales and marketing practices for Temodar, from September 1999 through December 2003, Schering knowingly and willfully offered and paid various forms of illegal remuneration to physicians and physicians' practices to induce utilization of Temodar for brain tumors and brain metastases, including, for example, improper preceptorships, advisory boards, entertainment, and placement of clinical studies in violation of 42 U.S.C. §1320a-7b(b)(2). Furthermore, the Government contends that, during this time period, Schering knowingly caused the submission of false or fraudulent claims for Temodar to the Medicaid and TRICARE Programs and caused the DVA to purchase Temodar by providing

physicians and physicians' practices with illegal remuneration to induce them to prescribe Temodar for patients;

(vii) The United States contends that, during the period September 1999 through December 2003, Schering knowingly promoted the sale and use of Temodar for brain metastases and certain brain tumors (including, specifically, newly-diagnosed anaplastic astrocytomas and a certain subset of glioblastoma multiformes), uses for which the Food and Drug Administration ("FDA") had not approved Temodar; i.e., Schering promoted Temodar for "unapproved" or "off-label" uses. The Government further contends that such off-label marketing violated the Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331 (a) and (d). The United States further contends that the use of Temodar for brain metastases during this time period, and the use of Temodar for certain brain tumors during the portion of this time period prior to 2002, were not medically-accepted indications, as defined in 42 U.S.C. § 1396r-8(k)(6), and that certain State Medicaid Programs could not reimburse these uses. The Government further contends that Schering knowingly caused the submission of false or fraudulent claims for Temodar to the TRICARE, FEHBP, and Medicaid programs for non-reimbursable uses, and caused the DVA to purchase Temodar dispensed to patients for unapproved indications; and

(viii) The United States contends that, as part of Schering's sales and marketing practices for Intron A for superficial bladder cancer from September 1999 through December 2003, Schering knowingly and willfully offered and paid various forms of illegal remuneration to physicians and physicians' practices to induce the utilization of Intron A for superficial bladder cancer including, for example, improper preceptorships, advisory boards, entertainment, and placement of clinical studies in violation of 42 U.S.C. § 1320a-7b(b)(2), and encouragement of

improper billing by physicians of Intron A vial overfill and free drugs. The Government further contends that Schering promoted Intron A for superficial bladder cancer although Schering did not have approval from the FDA for use in that indication. Furthermore, the Government contends that, during this time period, Schering knowingly caused the submission of false or fraudulent claims to the Medicaid, Medicare, and TRICARE Programs for Intron A and caused the DVA to purchase Intron A by inducing physicians to prescribe it to patients with superficial bladder cancer by providing them with such illegal remuneration.

Schering's conduct as described in the Information in the Federal Criminal Action and Preamble Paragraph H is hereafter referred to as the "Covered Conduct."

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- I. WHEREAS, HHS-OIG contends that it has certain administrative claims against Schering, as specified in Paragraphs 4 and 5 below, for engaging in the Covered Conduct.
- J. WHEREAS, this Agreement is neither an admission of facts or liability by Schering, with the exception of such admissions as Schering Sales Corporation makes in connection with a guilty plea to the Information referenced in Paragraph B above, nor a concession by the Government that its claims are not well founded.
- K. WHEREAS, to avoid the delay, expense, inconvenience, and uncertainty of protracted litigation of these claims, the Parties mutually desire to reach a full and final settlement as set forth below.

## III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations set forth below in this Agreement, and for good and valuable consideration as stated herein, the Parties agree as follows:

- 1. Schering agrees to pay to the United States, the Medicaid Participating States, and the PHS entities, collectively, the sum of two hundred fifty-five million twenty-five thousand, eighty nine dollars and sixty cents (\$255,025,089.60), plus interest in an amount of 4.292% per annum on the Federal Settlement Amount and Medicaid State Settlement Amount as further set forth in subparagraphs A and B below (\$29,527 per day) from July 27, 2005 and continuing until and including the day before complete payment is made (the "Settlement Amount"). This sum shall constitute a debt immediately due and owing to the United States and the Participating States on the Effective Date of this Agreement. This debt is to be discharged by payments to the United States and the Medicaid Participating States, under the following conditions:
- A. Schering shall pay to the United States the sum of one hundred fifty-nine million five hundred two thousand dollars (\$159,502,000), plus interest in an amount of 4.292% per annum (\$18,756 per day) from July 27, 2005, and continuing until and including the day before complete payment is made (the "Federal Settlement Amount").

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B. Schering shall pay to the Medicaid Participating States the sum of ninety-one million, six hundred two thousand dollars (\$91,602,000), plus interest in an amount of 4.292% per annum (\$10,771 per day) from July 27, 2005, until and including the day before complete payment is paid (the "Medicaid State Settlement Amount") under the terms and conditions of the Medicaid State Settlement Agreements. This Medicaid State Settlement Amount shall be paid into an interest bearing account as set forth in the Medicaid State Settlement Agreements no later than seven

business days after Schering receives written payment instructions from the National Association of Medicaid Fraud Control Units' Settlement Team for the Medicaid Participating States and following the latest of the dates on which the following occurs: (1) this Agreement is fully executed by the Parties and delivered to Schering's attorneys, or (2) the District Court accepts the Fed. R. Crim. P. 11(c)(1)(C) guilty plea in connection with the Criminal Action and imposes the agreed upon sentence. The Medicaid State Settlement Amount shall be paid to the Medicaid Participating States from the account following execution of the Medicaid State Settlement Agreements with all the Medicaid Participating States, or at any earlier date as otherwise agreed in writing between Schering and the National Association of Medicaid Fraud Control Units' Settlement Team.

- C. Schering shall pay to the PHS entities the sum of three million nine hundred twenty-one thousand eighty nine dollars and sixty cents (\$3,921,089.60) (the "PHS Settlement Amount"). Schering agrees to present for review and audit the underlying calculations used to determine the correct price(s) for the PHS entities during the relevant time periods. Schering agrees that if it is determined that Schering owes any additional amounts to any PHS entity, based upon the allegations in the Covered Conduct, Schering agrees to pay any additional amount required to make that entity whole. The PHS Settlement Amount shall be paid by Schering to each affected PHS entity by check within sixty (60) days following the latest of the dates on which the following occurs: (1) this Agreement is fully executed by the Parties and delivered to Schering's attorneys, or (2) the District Court accepts the Fed. R. Crim. P. 11(c)(1)(C) guilty plea in connection with the Criminal Action and imposes the agreed upon sentence.
- D. If Schering Sales Corporation's agreed upon guilty plea pursuant to Fed. R. Crim. P. 11(c)(1)(C) in the Criminal Action described in Preamble Paragraph B is not accepted by

the District Court or that Court does not impose the agreed upon sentence for whatever reason, this Agreement shall be null and void at the option of either the United States or Schering. If either the United States or Schering exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within five business days of the District Court's decision, the Parties will not object and this Agreement will be rescinded. If this Agreement is rescinded, Schering will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel or similar theories to any civil or administrative claims, actions or proceedings which are brought by the United States within 90 calendar days of notification to all other Parties of that rescission, except to the extent such defenses were available before February 5, 2003.

2. Subject to the exceptions in Paragraphs 3, 4, 6 and 7 below, and in consideration of the obligations of Schering set forth in this Agreement, conditioned upon Schering's payment in full of the Settlement Amount, subject to Paragraph 16 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment under this Agreement), and subject to the acceptance by the United States District Court for the District of Massachusetts of Schering Sales Corporation's guilty plea described in Preamble Paragraph B, the United States, on behalf of itself, and its officers, agents, agencies, and departments, agrees to release Schering, its predecessors, and its current and former parents, affiliates, divisions, subsidiaries, successors and assigns, and their current and former directors, officers, and employees, from any civil or administrative monetary claim that the United States has or may have under the False Claims Act, 31 U.S.C. §§ 3729-33; the Food Drug and Cosmetic Act, 21 U.S.C. §§ 331(a), 331(d) and 332; the Program Fraud Civil Remedics Act, 31 U.S.C. §§ 3801-12; the Medicaid Rebate Statute, 42

U.S.C. § 1396r-8; the Drug Pricing Program, 42 U.S.C. § 256b; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; any statutory provision applicable to federally-funded programs in this Agreement for which the Civil Division, Department of Justice has actual and present authority to assert and compromise pursuant to 28 C.F.R. Part O, Subpart I, 0.45(d)(1995); and common law claims for fraud, unjust enrichment, payment by mistake, or disgorgement for the Covered Conduct.

- 3. Notwithstanding any term of this Agreement, the United States specifically does not release any person or entity from any of the following claims or liabilities: (a) any criminal, civil, or administrative claims arising under Title 26, U.S. Code (Internal Revenue Code); (b) any criminal liability: (c) any liability to the United States (or any agencies thereof) for any conduct other than the Covered Conduct; (d) any claims based upon obligations created by this Agreement; (e) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs; (f) any express or implied warranty claims or other claims for defective or deficient products and services provided by Schering; (g) any claims for personal injury or property damage or for other consequential damages arising from the Covered Conduct; (h) any claim based on a failure to deliver items or services due; or (i) any civil or administrative claims against individuals, including current and former directors, officers, and employees of Schering, its predecessors, subsidiaries, and affiliates, who receive written notification that they are the target of a criminal investigation, are criminally indicted or charged, or are convicted, or who enter into a criminal plea agreement.
- 4. In consideration of the obligations of Schering set forth in this Agreement, and the Corporate Integrity Agreement and Addendum thereto (collectively, "CIA"), conditioned on Schering's payment in full of the Settlement Amount, and subject to Paragraph 16 below (concerning

bankruptcy proceedings commenced within 91 days of the effective date of this Agreement or any payment under this Agreement), OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the Medicare, Medicaid, or other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Schering, and except for Schering Sales Corporation, its predecessors, and its current or former parents, affiliates, divisions, subsidiaries, successors, and assigns, under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law), or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks or other prohibited activities), for the Covered Conduct, except as reserved in Paragraph 3 above, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Schering from the Medicare, Medicaid, or other Federal health care program under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 3 above.

5. In compromise and settlement of the rights of OIG-HHS to exclude Schering Sales Corporation pursuant to 42 U.S.C. § 1320a-7(a)(1)(mandatory exclusion for a criminal offense related to the delivery of an item or service under Medicare or Medicaid) based on the Plea Agreement described in Paragraph II.B. above, and pursuant to 42 U.S.C. § 1320a-7(b)(7) based on the Covered Conduct described in Paragraph II.H above, Schering Sales Corporation agrees to be permanently excluded under these statutory provisions from Medicare, Medicaid, and all other Federal health care programs as defined in 42 U.S.C. § 1320a-7b(f). Such exclusion shall have national effect and shall also apply to all other federal procurement and nonprocurement programs. Federal health care programs shall not pay Schering Sales Corporation or anyone else for items or

services, including administrative and management services, furnished, ordered, or prescribed by Schering Sales Corporation in any capacity while Schering Sales Corporation is excluded. This payment prohibition applies to Schering Sales Corporation and anyone who employs or contracts with Schering Sales Corporation. The exclusion applies regardless of who submits the claims or other request for payment. Schering Sales Corporation shall not submit or cause to be submitted to any Federal health care program any claim or request for payment for items or services, including administrative and management services, furnished, ordered, or prescribed by Schering Sales Corporation during the exclusion. Violation of the conditions of the exclusion may result in criminal prosecution and imposition of civil monetary penalties and assessments. Schering Sales Corporation further agrees to hold the Federal health care programs, and all federal beneficiaries and/or sponsors, harmless from any financial responsibility for goods or services furnished, ordered, or prescribed to such beneficiaries or sponsors during the exclusion. Schering Sales Corporation waives any further notice of the exclusion and agrees not to contest such exclusion either administratively or in any state or federal court. Schering Sales Corporation has been excluded since October 20, 2005, and the exclusion, as set forth in this Paragraph, shall continue permanently hereafter.

6. In consideration of the obligations of Schering set forth in this Agreement, conditioned upon Schering's full payment of the Settlement Amount, and subject to Paragraph 16 below (concerning bankruptcy proceedings commenced within 91 days of the effective date of this Agreement or any payment under this Agreement), TMA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion or suspension from the TRICARE Program against Schering, its predecessors, its current or former parents, affiliates, divisions, subsidiaries, successors and assigns, and their current and former directors, officers, and

employees, under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph 3 above, and as reserved in this Paragraph. TMA expressly reserves its authority under 32 C.F.R. § 199.9(f)(1)(i)(A) and (f)(1)(i)(B) based upon the Covered Conduct, and under 32 C.F.R. § 199.9(f)(1)(iii) if any entity is excluded by OIG-HHS pursuant to 42 U.S.C. § 1320a-7(a). Nothing in this Paragraph precludes TMA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 3, above.

- 7. In consideration of the obligations of Schering set forth in this Agreement, conditioned upon Schering's full payment of the Settlement Amount, and subject to Paragraph 16 below (concerning bankruptcy proceedings commenced within 91 days of the effective date of this Agreement or any payment under this Agreement), OPM agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking debarment from FEHBP against Schering, its predecessors, its current or former parents, affiliates, divisions, subsidiaries, successors and assigns, and their current and former directors, officers, and employees, under 5 U.S.C. § 8902a or 5 C.F.R. Part 890 for the Covered Conduct, except as reserved in Paragraph 3 above, and except if excluded by the OIG-HHS pursuant to 42 U.S.C. § 1320a-7(a). Nothing in this Paragraph precludes OPM from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 3, above.
- 8. The Parties each represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.
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- 10. Schering waives and shall not assert any defense it may have to criminal prosecution or administrative action relating to the Covered Conduct, which defense may be based in whole or in part on a contention that, under the Double Jeopardy Clause of the Fifth Amendment of the Constitution or the Excessive Fines Clause of the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.
- 11. In consideration of the obligations of the United States set forth in this Agreement, Schering, on behalf of itself and its predecessors, its current and former parents, affiliates, divisions, subsidiaries, successors and assigns fully and finally releases, waives and discharges the United States, its agencies, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) which Schering has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to or arising from the United States' investigation and prosecution of [Redacted], the Federal Criminal Action, and the Covered Conduct.
  - 12. The Settlement Amount that Schering must pay pursuant to Paragraph 1 above will

not be decreased as a result of the denial of claims for payment now being withheld from payment by any State or Federal payer, related to the Covered Conduct; and, if applicable, Schering agrees not to resubmit to any State and Federal payer any previously denied claims, which denials were based on the Covered Conduct, and agrees not to appeal or cause the appeal of any such denials of claims.

## 13. Schering agrees to the following:

<u>Unallowable Costs</u> Defined: that all costs (as defined in the Federal a. Acquisition Regulation ("FAR"), 48 C.F.R. § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Schering, its predecessors, parents, divisions, subsidiaries, or affiliates, and its present or former officers, directors, employees, and agents in connection with: (1) the matters covered by this Agreement and the related Plea Agreement; (2) the United States' audit and civil and criminal investigation relating to matters covered by this Agreement; (3) Schering's investigation, defense, and any corrective actions undertaken in response to the United States' civil and criminal investigations in connection with the matters covered by this Agreement (including attorneys' fees); (4) the negotiation and performance of this Agreement, the Plea Agreement, and the Medicaid State Settlement Agreement; (5) the payments made to the United States or any State pursuant to this Agreement, the Plea Agreement, or the Medicaid State Settlement Agreement and Release and any payments that Schering may make [Redacted]; and (6) the negotiation of and obligations undertaken pursuant to the CIA to: (a) retain an independent review organization to perform annual reviews as described in Section III of the ClA; and (b) prepare and submit reports to the OIG-HHS, are unallowable costs on Government contracts

with DVA and other agencies and under the Medicare Program, Medicaid Program, TRICARE Program, and FEHBP. However, nothing in this Paragraph affects the status of costs that are not allowable based on any other authority applicable to Schering. (All costs described or set forth in this Paragraph are hereafter, "Unallowable Costs").

- b. <u>Future Treatment of Unallowable Costs</u>: If applicable, these Unallowable Costs shall be separately estimated and accounted for by Schering and Schering shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Schering, its predecessors, divisions, subsidiaries, or affiliates to Medicare, Medicaid, TRICARE, FEHBP or DVA.
- c. Treatment of Unallowable Costs Previously Submitted for Payment: If applicable, Schering further agrees that within 60 days of the Effective Date of this Agreement, it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid, DVA, and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid Program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Schering, its predecessors, parents, divisions, subsidiaries, or affiliates and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Schering agrees that the United States, at a minimum, shall be entitled to recoup from Schering any overpayment, plus applicable interest and penalties, as a result of the inclusion of such Unallowable Costs on previously-submitted cost

reports, information reports, cost statements, or requests for payment. Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice, and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Schering or its parents, divisions, subsidiaries or affiliates on the effect of inclusion of Unallowable Costs on Schering or its divisions, subsidiaries or affiliates' cost reports, cost statements, or information reports. Nothing in this Agreement shall constitute a waiver of the rights of the United States to examine or re-examine the Unallowable Costs described in this Paragraph.

- 14. Schering agrees that it shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors. Schering waives any causes of action against these beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims for payment covered by this Agreement.
- 15. Schering expressly warrants that it has reviewed its financial condition and that it is currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(B)(ii)(I), and shall remain solvent following payment of the Settlement Amount. Further, the Parties expressly warrant that, in evaluating whether to execute this Agreement, the Parties (a) have intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Schering within the meaning of 11 U.S.C. § 547(c)(1), and (b) have concluded that these mutual promises, covenants and obligations do, in fact, constitute such a contemporaneous exchange.
  - 16. In the event Schering commences, or another party commences, within 91 days of the

Effective Date of this Agreement or any payment made hereunder, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking to have any order for relief of Schering's debts, or seeking to adjudicate Schering as bankrupt or insolvent, or (b) seeking appointment of a receiver, trustee, custodian or other similar official for Schering or for all or any substantial part of Schering's assets, Schering agrees as follows:

- a. Schering's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. §§ 547 or 548, and Schering shall not argue or otherwise take the position in any such case, proceeding or action that: (i) Schering's obligations under this Agreement may be avoided under 11 U.S.C. §§ 547 or 548; (ii) Schering was insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment made to the United States hereunder; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to Schering.
- b. If Schering's obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases provided in this Agreement, and bring any civil and/or administrative claim, action or proceeding against Schering for the claims that would otherwise be covered by the releases provided in this Agreement. If the United States chooses to do so, Schering agrees that for purposes only of any claims, actions or proceeding referenced in this first clause of this Paragraph (i) any such claims, actions, or proceedings brought by the United States (including any proceedings to exclude Schering from participation in Medicare, Medicaid, or other Federal health care programs) are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceeding

described in the first clause of this Paragraph, and that Schering shall not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) Schering shall not plead, argue, or otherwise raise any defenses under the theories of statue of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceedings which are brought by the United States within 90 calendar days of written notification to Schering that the releases herein have been rescinded pursuant to this Paragraph, except to the extent such defenses were available before February 5, 2003; and (iii) the United States and the Participating States have a valid claim against Schering in the amount of two hundred fifty-five million twenty five thousand eighty nine dollars and sixty cents (\$255,025,089.60) plus applicable multipliers and penalties and they may pursue their claims, inter alia, in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action or proceeding; and

- c. Schering acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement.
- 17. Except as otherwise stated in this Agreement, this Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any claims against any other person or entity.
- 18. Nothing in this Agreement constitutes an agreement by the United States concerning the characterization of the amounts paid hereunder for purposes of the Internal Revenue laws, Title 26 of the United States Code.
- 19. Each party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

20. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement shall be the United States District Court for the District of Massachusetts

[Redacted]

except that disputes rising under the CIA shall be resolved exclusively through the dispute resolution provisions set forth in the CIA.

21. [Redacted]

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- 22. The undersigned Schering and Schering Sales Corporation signatories represent and warrant that they are authorized by their respective Board of Directors to execute this Agreement. The undersigned United States signatories represent that they are signing this Agreement in their official capacities and they are authorized to execute this Agreement on behalf of the United States through their respective agencies and departments.
  - 23. The "Effective Date" of this Agreement shall be on the date of signature of the last

signatory to the Agreement. Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

- 24. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.
- 25. This Agreement shall not be amended except by written consent of the Parties, except that only Schering and OIG-HHS must agree in writing to modification of the CIA, without the consent of any other party to this Agreement or the Plea Agreement.
- 26. Schering hereby consents to the disclosure of this Agreement and information about this Agreement by the United States to the public.
- 27. This Agreement may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same Agreement

#### UNITED STATES OF AMERICA

By:

SUSAN WINKLER

JENNIFER BOAL

GREGG SHAPIRO

Assistant U.S. Attorneys
United States Attorney's Office
District of Massachusetts

By:

ANDY J. MAO

Trial Attorney, Civil Division
United States Department of Justice

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Assistant U.S. Attorneys
United States Attorney's Office
District of Massachusetts

By:

ANDY J. MAO
Trial Attorney, Civil Division
United States Department of Justice

Ву:	EUGENE THIROLF Director, Office of Consumer Litigation United States Department of Justice	Dated: 8/23/2006
Ву:	GREGORY E. DEMSKE Assistant Inspector General for Legal Affairs Office of Counsel to the Inspector General U.S. Department of Health and Human Services	Dated:
Ву:	LAUREL C. GILLESPIE Deputy General Counsel TRICARE Management Activity United States Department of Defense	Dated:
Ву:	KATHLEEN McGETTIGAN Deputy Associate Director Center for Retirement & Insurance Services United States Office of Personnel Management	Dated:
Ву:	J. DAVID COPE Assistant Inspector General for Legal Affairs United States Office of Personnel Management	Dated:

By: Dated: EUGENE THIROLF Director, Office of Consumer Litigation United States Department of Justice Dated: 8/25/06 By: GREGORY E. DEMSKE Assistant Inspector General for Legal Affairs Office of Counsel to the Inspector General U.S. Department of Health and Human Services By: Dated: LAUREL C. GILLESPIE Deputy General Counsel TRICARE Management Activity United States Department of Defense By: Dated: KATHLEEN McGETTIGAN Deputy Associate Director Center for Retirement & Insurance Services United States Office of Personnel Management By: Dated: J. DAVID COPE Assistant Inspector General for Legal Affairs

United States Office of Personnel Management

Ву:	EUGENE THIROLF Director, Office of Consumer Litigation United States Department of Justice	Dated:
Ву:	GREGORY E. DEMSKE Assistant Inspector General for Legal Affairs Office of Counsel to the Inspector General U.S. Department of Health and Human Services	Dated:
Ву:	LAUREL C. GILLESPIE Deputy General Counsel TRICARE Management Activity United States Department of Defense	Dated: 25 And Long
Ву:	KATHLEEN McGETTIGAN Deputy Associate Director Center for Retirement & Insurance Services United States Office of Personnel Management	Dated:
Ву:	J. DAVID COPE Assistant Inspector General for Legal Affairs United States Office of Personnel Management	Dated:

Schering-Plough Corporation - Civil Settlement Agreement

Ву:	EUGENE THIROLF Director, Office of Consumer Litigation United States Department of Justice	Dated:
Ву:	GREGORY E. DEMSKE Assistant Inspector General for Legal Affairs Office of Counsel to the Inspector General U.S. Department of Health and Human Services	Dated:
Ву:	LAUREL C. GILLESPIE Deputy General Counsel TRICARE Management Activity United States Department of Defense	Dated:
Ву:	KATHLEEN McGETTIGAN Deputy Associate Director Center for Retirement & Insurance Services United States Office of Personnel Management	Dated: 8/24/06
ву.	J. DAVID COPE Assistant Inspector General for Legal Affairs United States Office of Personnel Management	Dated: 8 24 06

#### SCHERING-PLOUGH CORPORATION

By:

THOMAS J. SABATING

Executive Vice President and General Counsel

Schering-Plough Corporation

Dated:

8/25/06

By:

BRIEN O'CONNOR JOAN MCPHEE JOSHUA LEVY Ropes & Gray

Counsel to Schering-Plough Corporation

Dated:

8/25/06

SCHERING SALES CORPORATION

By:

BRENT SAUNDERS

President

Schering Sales Corporation

Dated:

8/25/06

By:

BRIEN O'CONNOR
JOAN MCPHEE
JOSHUA LEVY
Ropes & Gray
Counsel to Schering Sales Corporation

Dated:

8/25/06